



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Office of Policy, Planning, and
Legislation HF-1 1
5600 Fishers Lane
Rockville, MD 20857

JUN 20 2002

Peter Barton Hutt, Esq.
Covington & Burling
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401

Re: Docket No. 98N-0583

Dear Mr. Hutt:

This letter is in regard to your Petition for Reconsideration and Stay of Action, dated June 17, 2002, in which you requested both reconsideration and a stay of two provisions in the final export notification and recordkeeping rule. The final rule appeared in the *Federal Register* on December 19, 2001 (66 Fed. Reg. 65429) and was originally supposed to become effective on March 19, 2002. In response to one letter and three petitions for stay of action from various parties (including the Cosmetic, Toiletry, and Fragrance Association), the Food and Drug Administration (FDA) extended the effective date to June 19, 2002 (67 Fed. Reg. 34387 (May 14, 2002)).

Your petition raises complex issues. Consequently, while the agency considers those issues, we intend to exercise enforcement discretion and not generally take enforcement action for thirty days from the June 19, 2002, effective date (up to and including July 19, 2002) as follows:

(1) regarding the last sentence of 21 CFR 1.101(b), "The records shall be made available to the Food and Drug Administration, upon request, during an inspection for review and copying by FDA," with respect to foods and cosmetics exported under or subject to section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (Act) only; and

(2) regarding 21 CFR 1.101(b)(2).

98N-0583

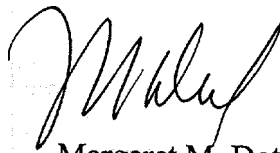
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Mr. Hutt

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Please be advised, however, that the exercise of enforcement discretion will pertain solely to the specific requirements as listed above. Affected parties must continue to comply with the other requirements in 21 CFR 1.101 and with the statutory requirements for exports under sections 801(e) and 802 of the Act.

Sincerely,



Margaret M. Dotzel
Associate Commissioner for Policy